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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Christine Nicol

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/806,915	Applicant(s) NICOL ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/22/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-18,20-25,28-30 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of IDS, request for extension of time, request for continued examination and remarks, all filed 1/22/09. No claim is amended. Claims 1, 2, 7-18, 20-25, 28-30 and 34 are pending.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 8 recites "below about 20%" with the range recited encompassing two ranges, one that is about 20% and one that is below 20%. For example, 2% is below 20% and would meet the limitation of below 20% while 2% cannot meet the limitation of about 20%. Therefore, the meets and bounds of the protection sought in claim 8 are not clearly set forth in the claim.

Correction is respectfully requested.

4. Claims 12, 13, 16-18 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 12, 13, 16 and 17 recite the limitation "the stomach pH" in lines 1 (claims 12 and 13), lines 1 and 2 (claims 16 and 17). There is insufficient antecedent basis for this limitation in the claim.

Claims 12, 13, 16 and 17 depend on claim 34 and claim 34 does not recite "stomach pH."

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert et al. (6,284,265).

8. Claim 1 is a composition comprising fat in an amount of from about 5% to about 20% by weight; fiber in an amount of from about 15% to about 70% by weight and some of the fiber is chopped fiber; and stomach antacid. Oral feed is the route of administration of the composition for the intended use of the composition.

9. Lambert discloses an antacid composition that comprises antacid, 4.0-8.0% oil, antioxidant, and 46.0-84.5% carrier (column 2, lines 1-34; column 2, lines 5-47 and claims 1-3). The antacid is selected from the group consisting of aluminum phosphate, dihydroxy-aluminum-

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sodium-carbonate, dicalcium phosphate, calcium carbonate and mixtures thereof (column 2, lines 1-4, 48-52). The carrier is selected from the group consisting of ground wheat, spray dried whey, steam rolled oats and mixtures thereof (column 2, lines 11-13; column 3, lines 16-18).

The antacid such as calcium carbonate is a stomach antacid meeting the requirement of the claimed composition to have stomach antacid; the carrier such as ground wheat or rolled oats or mixtures thereof meets the limitation of fiber and the amount of 46-84.5% of carrier, and specifically the 60.45%, derived from 30-45% ground wheat and 20.0% rolled oats (column 2, lines 33 and 34) meet the limitation of 15-70% fiber or points within the disclosed range of 46-84.5% intersects points within the claimed range of 15-70% fiber of claims 1, 2. Points within the disclosed amount of 4-8% oil intersects points within the recited range of 5-20% oil, thus meeting the requirements of 5-20% oil of claims 1, 2. The presence of carbohydrate in oats meets the requirement of starch in claim 8 since in one of the embodiments of Lambert, the rolled oat is present about 20% such that the amount of the carbohydrate is less than 20% because oats is comprised of fiber and carbohydrate. The composition of Lambert is administered to horses to reduce gastric acid (column 1, lines 52-54). Inhibiting gastric acid secretion as recited in claim 9 is what the composition will do in the stomach of horses, and in this respect the composition of Lambert would also inherently do that but as noted, Lambert specifically teaches that the antacid in composition reduces gastric acid levels (column 2, lines 53, 54).

10. Claim 11 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lambert et al. (6,284,265).

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11. Lambert is described above as administering composition comprising antacid to reduce gastric acid levels. Claim 11 treats or ameliorates animal stereotypy by controlling the stomach pH by oral administration of stomach antacid. Thus it is the antacid that produces the effect of controlling the stomach pH that leads to the treatment or amelioration of stereotypy. Therefore, the antacid composition of Lambert would inherently treat or ameliorate animal stereotypy, in this case, stereotypy in the horse, by the antacid composition orally administered to reduce gastric acid levels. In the alternate, while Lambert did not specifically state treatment or amelioration of animal stereotypy, it is the antacid composition that reduces or controls stomach pH of the animal that produces the effect of treatment or amelioration of animal stereotypy, so that because Lambert's antacid composition administered orally reduces gastric acid levels, treatment or amelioration of stereotypy in the horse animal would intrinsically be produced. Therefore, it would be prima facie to expect that reduction in acid levels of the stomach would produce the expected treatment or amelioration of stereotypy in the horse animal.

12. Claims 34, 17, 19 and 28-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35).

13. Winskill discloses feeding horse with food composition in pelleted form and the food comprises 100 g protein, 200 g fiber, 27.5 g oil and 85 g ash in addition to feeding the horse on concentrates and "timothy hay" (pages 27 and 28). The horses in Winskill exhibited stereotypic behavior and in the abstract in Winskill it is suggested that stereotypy may be caused by the horse's inability to express foraging behavior (lines 1 and 2 of the abstract). In Winskill's study, the horses expressed foraging behavior when fed the feed comprising fiber and oil (fat). Horse

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belongs to the taxonomic family of horses known as equidae so that claim 28 is met. Claims 29 and 30 are also met because Winskill teaches cribbing of horses as stereotypic behavior in horses.

14. Claim 34 is directed to a method of treating or ameliorating stereotypic behavior in an animal. The method of claim 34 comprises orally administering a composition comprising fat and fiber to control pH of the stomach. Stomach antacid is optional. Thus, treatment or amelioration of stereotypy or minimization of risk of an animal developing stereotypy is the effect of the composition that is administered orally to the animal.

15. Thus, the composition of Winskill that is administered to the horse animal would also inherently produce the effect of treatment or amelioration of stereotypy or minimization of risk of the horse developing stereotypy noting that Winskill mentions confined horses show stereotypic behaviors. However, in the alternate, because Winskill did not describe verbatim treatment or amelioration of animal stereotypy, and because the method of claim 34 administers composition comprising fiber and oil to produce the effect of treatment or amelioration of stereotypy or minimization of risk of an animal developing stereotypy, oral administration of the composition of Winskill comprising fiber and oil would intrinsically produce the effects expected from the composition thereby rendering the process obvious in the alternative.

16. Claims 24 and 25 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

17. Pagan teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or

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prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Instant claim 11 is interpreted as a method of treatment or amelioration of stereotypy, the method comprising administering a composition that contains antacid to control stomach pH of an animal for examination purposes. The method of claim 24 minimizes or reduces ulcer formation. Pagan administers an antacid composition to treat ulcers. Since the method of treatment or amelioration of animal stereotypy involves reduction or minimization of ulcer, then by treating or minimizing the ulcer in the horse animal would inherently produce the effect of treatment or amelioration of animal stereotypy. However, in the alternate, because Pagan does not specifically say treatment or amelioration of stereotypy, and because the claim says that stereotypy is treated or ameliorated ulcer formation is reduced or minimized, it flows that the treatment and minimization or prevention of gastric ulcer by Pagan would also intrinsically treat or ameliorate stereotypy in the horse animal thereby rendering the process obvious in the alternative.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1, 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Brever et al. (US 3,946,115).

21. Lambert is described above. Lambert does not describe the size of the wheat or rolled oats. Lambert does not state the size/length of the antacid composition. But horse feeds are generally extruded and when extruded, these feeds have certain dimensions of length. For example, Brever discloses extruded horse feed as having size and shape and in this particular instance, the length of the extrudate ranges from 1/8 inches to 3 inches (0.318 to 7.62 cm).

Thus, taking the teachings of Lambert and the disclosure of Brever relied upon for teaching that horse feeds are extruded, one having ordinary skill in the art at the time the invention was made has the technical capability to use known extrusion technique and extrusion device to prepare the composition of Lambert so that the resulting extrudate would have certain dimensions as per the geometrical design of the device; In the case of the Brever reference, the size would range from 1/8 inches to 3 inches (0.318 to 7.62 cm).

22. Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

23. Lambert was described above to anticipate claims 1, 2 and 9. Lambert teaches calcium carbonate stomach antacid for reducing gastric acid. Lambert does not use the proton pump

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inhibitor or histamine type-2 antagonist as the stomach antacid as recited in claim 10. But stomach antacid can be used in place of the other to achieve the same effect of gastric acid reduction. And, Pagan specifically teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Therefore, taking the teachings of Lambert and Pagan, one having ordinary skill in the art at the time the invention was made would reasonably expect that histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161) for the carbonate antacid of Lambert would produce the expected reduction of gastric acid.

24. Claims 11-17, 23-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265).

25. Lambert has been described above as anticipating claim 11 or in the alternate rendering obvious claim 11. Lambert does not specifically state the periods when the antacid composition is administered to reduce the stomach acid. Since the horses placed in the study, the horses have to have been weaned although the art is silent on that, and the examiners position is that the horses in Lambert's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15 or before birth as recited in claim 12. Regarding claims 12 and 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior (claim 13) or before the stereotypic behavior is

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permanent or “fixed” as recited in claim 12 since it is the administration of the composition in claim 34 that results in the control of the pH. For claim 17, the antacid composition of Lambert that is orally administered intrinsically inhibits the secretion of the acid in the stomach.

Therefore, taking the teaching of Lambert, claims 12-16 would be prima facie obvious since it is the reduction in the acidity that produces the various effects and the time of administration of the feed would be any of the periods recited in the claims 12-16.

26. Claims 11, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,284,265) in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998).

27. Lambert was described above to anticipate claim 11. Lambert teaches calcium carbonate stomach antacid for reducing gastric acid. Lambert does not use the proton pump inhibitor or histamine type-2 antagonist as the stomach antacid as recited in claim 18. But one stomach antacid can be used in place of the other to achieve the same effect of gastric acid reduction. And, Pagan specifically teaches treating equine ulcers by neutralizing acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161). Therefore, taking the teachings of Lambert and Pagan, one having ordinary skill in the art at the time the invention was made would reasonably expect that histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox (pages 160 and 161) for the carbonate antacid of Lambert would produce the expected reduction of gastric acid.

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28. Claims 34, 12-17, 20-23 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35).

29. Winskill has been described above to anticipate claims 34, 17, 19 and 28-30 or in the alternate render the claims obvious by rendering the method of claim 34 obvious. Since the horses were purchased and placed in the study, the horses have to have been weaned although the art is silent on that, and the examiners position is that the horses in Winskill's study encompasses the scope of recently weaned or weaning as recited in claim 14 or being weaned as recited in claim 22 or following weaning as recited in claim 23 or weaned as recited in claim 15 or before birth as recited in claim 12. Regarding claims 12 and 13, examiner takes the position that the stomach pH of the horse is controlled before or shortly after the horse develops stereotypic behavior (claim 13) or before the stereotypic behavior is permanent or "fixed" as recited in claim 12 since it is the administration of the composition in claim 34 that results in the control of the pH. For claim 17, the composition of Winskill that is orally administered intrinsically inhibits the secretion of the acid in the stomach. Therefore, taking the teaching of Winskill, claims 12-16 would be prima facie obvious since it is the reduction in the acidity that produces the various effects and the time of administration of the feed would be any of the periods recited in the claims 12-16.

Response to Arguments

30. Applicant's arguments filed 1/22/09 have been fully considered but they are not persuasive. Applicant's arguments with respect to Winskill and Pagan as the arguments apply to the current rejections will be addressed.

31. Winskill: Applicant argues that Winskill does not associate animal stereotypy and acidity of the intestinal tract. The examiner agrees that Winskill does not associate animal stereotypy and acidity of the intestinal tract. But claim 34, is directed to a method that treats or ameliorates animal stereotypy by controlling stomach pH by oral administration of a composition that comprises fat and fiber. Thus a composition comprising fiber and fat when orally administered to the animal would control the pH of the stomach and inherently produce the effect of treating or ameliorating animal stereotypy deriving from the effect of the composition. Therefore, oral administration of a composition comprising fiber and oil by Winskill to the horse animal would inherently produce the effect of treating and ameliorating stereotypy in the horse animal.

32. Johnson is not currently applied as art against the claims and the arguments as they apply to Johnson are moot.

33. Pagan: Applicant argues that there is no disclosure in Pagan that inhibition of gastric acid secretion or treatment of gastric ulcer will lead to the treatment of stereotypy and that applicant is unable to find any link in Pagan that links formation of ulcers with stereotypy. While the examiner agrees that Pagan does not state verbatim that inhibition of gastric acid secretion or treatment of gastric ulcer leads to treatment of stereotypy, it is noted that claim 24 treats or ameliorates animal stereotypy by minimizing or reducing ulcer formation or treating ulcers. Thus, a prior art that reduces ulcer formation or treats ulcer would inherently treat or

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ameliorate animal stereotypy. Therefore, Pagan inherently teaches ameliorating or treating horse animal stereotypy by reducing or inhibiting gastric acid secretion or treating gastric ulcer. While also, Pagan does not specifically link gastric ulcers with stereotypy, it is known in the art that gastric discomfort leads to stereotypic behavior such as crib-biting and wood chewing as evidenced by Burkard (Ref. Attached) and it is noted that the applicant has not factually shown that gastric ulcers in the horse do not contribute to stereotypy. Applicant's arguments with respect to Pagan and hindgut acidity are moot in view of the current rejections.

34. For claims 1 and 2: Applicant argues that the composition of Winskill does not contain antacid. The examiner agrees and this argument is moot because Winskill is not used as art against claims 1 and 2. But the examiner stands firm that "for use in the treatment or amelioration of animal stereotypy" is an intended use of the composition because claims 1 and 2 are composition/product claims and not method claims except applicant wants to say on the record that claims 1 and 2 are method claims.

35. Evidence from the examiner linking stomach acidity and stereotypy: When a rejection is made that gastric acid contributes to stereotypy in view of what is taught in the prior art, the burden shifts to the applicant to factually show otherwise noting that the PTO does not have laboratories. However, for the sake of completeness, the current rejection does not say that any of the currently cited references says that gastric ulcer leads to stereotypy. However, the claims recite that reduction in gastric acid or treatment of ulcers acid produces amelioration or treatment of stereotypy, see at least instant claims 24, 25, 17. Furthermore, it is known in the art that gastric discomfort leads to stereotypic behavior such as crib-biting and wood chewing as evidenced by Burkard (Ref. Attached). The burden is on applicant to show that gastric acidity

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does not contribute to stereotypy. While the examiner agrees with the applicant that neither Winskill nor Pagan links intestinal acidity to stereotypy in haec verbis, it is also noted that the applicant has failed to factually show that there is no link between gastric acidity and stereotypy and even consideration of what is known in the art (see Burkard).

36. Declaration by Dr. Harris 2006:

The declaration by Dr. Harris filed 10/11/2006 was fully addressed and reproduced for applicant's benefit in the last office action (7/22/2008) and is again reproduced herein below.

Declaration by Dr. Harris 2008, 08 April:

37. The declaration under 37 CFR 1.132 filed 4/30/08 is insufficient to overcome the rejection of claims 1, 2, 7-18, 20-25, 28-30 and 34 based upon the rejections under 35 U.S.C. 103(a) as being unpatentable over Winskill et al. (In Applied Animal Behavior Science, 1996, Vol. 48, pp 25-35) in view of Johnson et al. (In Equine Veterinary Journal, 1998, MARCH, Vol. 30 (2) 139-143) further in view of Pagan (In Australian Equine Veterinarian, Vol. 16 (4) Summer 1998) as set forth in the last Office action because: i) Winskill discloses the composition of the claims 1 and 2 except that the composition does not contain sodium carbonate. The result of feeding horses with feed composition containing fiber, oil (fat) and protein is a reduction in stall-walking or stereotypy according to the rejection of record and found in the whole document of Winskill with emphasis on the abstract; pages 27, 28, 32, 33. ii) while Johnson may not have literally stated relationship between gastric acidity and equine stereotypy, it is noted that Johnson notes that horses fed with Founderguard had a drop fecal pH (abstract; pages 140-142), and reduction in abnormal behaviors such as wood chewing, grasping and bed eating, cribbing, wind-sucking (see the whole document of Johnson, with emphasis of

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page 140, left column; page 142, right column; and page 143, left column); Johnson further notes that it is known in the art that administration of sodium carbonate lowers the incidence of stereotypy (page 139, right column), which is a suggestion that sodium bicarbonate when administered would lower the incidence of stereotypy. It is further noted that Johnson orally feeds the horses. iii) since Johnson suggests that sodium carbonate administration lowers stereotypy and since the horses in Johnson are fed orally and since Winskill orally feeds horses that lead to reduction in stall-walking (stereotypy), the artisan would have reasonable expectation of success that addition of sodium carbonate to the feed of Winskill would lower the incidence of stall-walking. iv) regarding Pagan, it is noted that the title of the clinical paper is “Gastric Ulcers in Horses: A Widespread but Manageable Disease (page 159) and page 160, the title of the second full paragraph states: “Gastric Acid is a Major Cause.” Pagan was relied upon for teaching neutralizing gastric acidity with histamine type-2 antagonists (cimetidine and ranitidine) or proton pump inhibitors such as omeprazole or prostaglandin analogues or equine antacid such as the patented antacid Neigh-Lox and the above three classes of drugs inhibit gastric secretion (pages 160 and 161). v) while applicant is of the opinion that a link between hindgut acidity and stereotypy in the horse would not have led the skilled artisan to believe that there is also a link between stomach acidity and stereotypy, it is noted that applicant has not provided factual evidence that there is no link between stomach acidity and stereotypy. It is known in the art and presented in the rejections that feeding horses with diets of fat and fiber and protein lowers fecal pH and incidence of stereotypy; and administration of sodium carbonate lowers the incidence of stereotypy. vi) the evidence provided by applicant on 10/11/06 would not have led the artisan away from including sodium carbonate in a feed for horses because there is a teaching

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that food containing protein and fiber and fat lowers fecal acidity and reduces stereotypy/stall-walking (Winskill) and another that teaches sodium carbonate lowers the incidence of stereotypy and hindgut acidity (Johnson). Further, the declaration by Dr. Harris (10/11/06) supports oral administration of sodium carbonate or the obvious addition of sodium carbonate to the feed of Winskill to reduce stall-walking/stereotypy.

38. Thus in all, the declaration is an opinion declaration that has not provided factual evidence as to why sodium carbonate cannot be administered orally to the horse, as to why the administration of sodium carbonate with a feed containing fat and fiber would not lower stereotypy and as to why the administration of sodium carbonate would not lower stereotypy as suggested by Johnson, and as to why there is no link between stomach acidosis and stereotypy in the horse.

39. Regarding oral administration of sodium bicarbonate: The applicant is referred to paragraph 9 above of the action where it is described that Lambert discloses an antacid composition that comprises antacid, 4.0-8.0% oil, antioxidant, and 46.0-84.5% carrier (column 2, lines 1-34; column 2, lines 5-47 and claims 1-3). The antacid is selected from the group consisting of aluminum phosphate, dihydroxy-aluminum-sodium-carbonate, dicalcium phosphate, calcium carbonate and mixtures thereof (column 2, lines 1-4, 48-52). The carrier is selected from the group consisting of ground wheat, spray dried whey, steam rolled oats and mixtures thereof (column 2, lines 11-13; column 3, lines 16-18). The antacid such as calcium carbonate is a stomach antacid meeting the requirement of the claimed composition to have stomach antacid; the carrier such as ground wheat or rolled oats or mixtures thereof meets the limitation of fiber and the amount of 46-84.5% of carrier, and specifically the 60.45%, derived

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from 30-45% ground wheat and 20.0% rolled oats (column 2, lines 33 and 34) meet the limitation of 15-70% fiber or points within the disclosed range of 46-84.5% intersects points within the claimed range of 15-70% fiber of claims 1, 2. The composition of Lambert is administered to horses to reduce gastric acid (column 1, lines 52-54). Therefore, it is known to administer antacid such as calcium carbonate to horses. The Lambert art was filed March 12, 1998 and claims priority to March 13, 1997. This appears to be the state of the art in March or 1997 before applicant's invention.

40. Regarding oral administration of sodium carbonate: Lambert orally administers calcium carbonate (priority date of 1997). The declaration continues to be ineffective in placing the claims in condition for allowance. Please refer to the reasons provided 12/21/06, reproduced 7/22/08 and herein.

41. Evidence of unexpected result, teaching away of the prior art and long felt need: The declaration continues to be insufficient to place the claims in condition for allowance in view of the rejections made herein. Lambert teaches the use of antacid in horses. Pagan uses antacid in the horse the horse to treat ulcer. Antacid is optional in claim 34. Claim 11 administers antacid to treat stereotypy and the consequence or effect of antacid is also be inherent or intrinsic to the antacid administered orally. Pagan, Winskill and Lambert, by administering the composition claimed to be administered to elicit the effect of treating stereotypy, also inherently or intrinsically treats stereotypy. There is no teaching away of these references in view of the claims.

42. Please note that no claim is amended with the filing of the RCE. New rejections are made and the claims are not allowable in view of the rejections.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618